

AUG 25 2008

510(k) Summary

TM-400

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

Submitter Name: ITO CO., LTD.
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Contact Name: KENNETH L. BLOCK, RAC

Date Prepared: August 15, 2008

Proprietary Name: TM-400

Common Name: Powered Traction Device

Classification Number: 21 CFR 890.5900

Class: II

Predicate Devices: K992545 –TM-300 Traction System (ITO. CO., LTD.)
K053223 –TX Traction (CHATTANOOGA GROUP)

Device Description:

The TM-400 is a simple to use powered traction unit that offers static, intermittent, and cycle traction with user-definable hold, rest and treatment times. The unit consists of a software-controlled electro-mechanical traction system. The physical characteristics of the TM-400 are substantially equivalent to the predicate traction devices including size, weight, materials of construction, and user interface. In addition, the unit has incorporated similar features as the predicate devices such as:

- Automatic calibration of traction force
- An internal memory that stores up to 30 treatment patterns
- Traction speed selectable from five preset values
- Eight traction modes
- Remote patient-controlled treatment shutoff switch
- Large and high-visibility LCD screen

The TM-400 traction device operates by attaching the cable hook to a harness accessory, which is in turn attached to the patient treatment area, for traction and mobilization of skeletal structures and skeletal muscles according to the detailed indications of use. Detailed comparison of specific TM-400 features and characteristics to the predicate devices is contained in Section 8 of this submission.

Intended Use:

The TM-400 device is intended to be used by medical professionals and facilities including in-patient and out-patient hospitals and clinics, chiropractors, physical therapists, sports rehabilitation clinics, occupational therapists, and other qualified users according to the detailed indications for use. Sale of the TM-400 is restricted to a licensed physician or licensed practitioner, or on the order or prescription of a physician or licensed practitioner.

Indications for Use:

Use of the TM-400 powered traction device is indicated for the following:

- Providing standard therapeutic and custom user-defined treatments in static, intermittent, progressive, regressive, cyclical and combination distraction forces to relieve pressures on structures that may be causing pain of skeletal or muscular origin (cervical, thoracic, lumbar, hip, wrist, shoulder).
- Providing traction and mobilization of skeletal structures and skeletal muscles.
- Relieving peripheral radiation / sciatica and pain associated with:

Discs:

- Protruding, bulging, herniated and prolapsed discs
- Degenerative disc disease
- Discogenic pain

Facets:

- Facet syndrome
- Posterior facet syndrome
- Acute facet problem

Muscles & Joints:

- Muscle pain and spasms
- Degenerative joint disease

Spinal Structures:

- Spinal root impingement
- Pinched nerves
- Compression fractures

Pain:

- Back, lower back, neck, joint, sciatic and radicular pain

Mobility & Flexibility:

- Hypomobility
- Limited spinal and joint flexibility

Cited Standards to Determine Substantially Equivalence:

Testing was carried out to assure compliance to FDA recognized electrical safety standards. ITO CO., LTD was issued a certificate of compliance to the UL60601-1 standards by TUV, which appears in Section 13 of this submission. In addition, ITO CO., LTD was issued an Attestation of Conformity for the TM-400 in regard to the IEC60601-1-2 standards for electromagnetic compatibility by TUV, which appears in Section 13 of this submission.

Non-Clinical Testing:

Non-clinical verification and validation testing was conducted on final TM-400 production units, and the results of such testing appear in Section 12 and Section 14 of this submission.

Truthful and Accuracy Statement:

Signed by a corporate management representative of the submitter, the required statement attesting to the truthfulness and accuracy of the information contained in Section 7 of this submission.

Further Information:

Please contact the following individual to request any further information regarding this submission:

Kenneth L. Block, RAC
Official Correspondent (ITO CO., LTD.)
Ken Block Consulting
1201 Richardson Dr.
Suite 140
Richardson, TX 75080
TEL: 972-480-9554
FAX: 972-767-4325
EMAIL: ken@kenblockconsulting.com



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 25 2008

ITO Co., Ltd.
% Ken Block Consulting
Mr. Kenneth L. Block, RAC
1201 Richardson Drive, Suite 140
Richardson, Texas 75080

Re: K081247
Trade/Device Name: TM-400
Regulation Number: 21 CFR 890.5900
Regulation Name: Power traction equipment
Regulatory Class: II
Product Code: ITH
Dated: July 7, 2008
Received: July 8, 2008

Dear Mr. Block:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Mr. Kenneth L. Block, RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081247 (pg 1/1)

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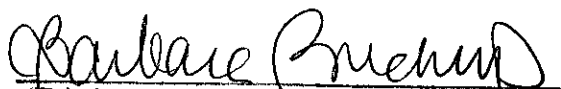
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K081247